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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,119	03/30/2001	June Kaplow	P23,461-A USA	9257

7590 04/18/2005
Patrick J. Kelly, Ph.D., Esquire
Synnestvedt & Lechner LLP
Suite 2600
1101 Market Street
Philadelphia, PA 19107-2950

EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,119

Applicant(s)

KAPLOW ET AL

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 4-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

1. Newly amended claims 26-28 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Original claims 26-28 were drawn to the generic "use" of a nucleic acid encoding an NFIF polypeptide, the claims were considered improper process claims since the claims did not set forth any steps involved in the process. Since the original claims were considered improper process claims, they were interpreted as being drawn to a nucleic acid encoding an NFIF polypeptide comprising an amino acid sequence of Figure 1 (SEQ ID NO: 1), and originally included in elected invention group I. Currently amended claims 26-28 now recite "[A] method for treatment or prevention of an NFkB-regulated inflammatory response in a patient comprising administering to said patient" a nucleic acid encoding, a recombinant vector comprising a nucleic acid encoding, or a defective recombinant viral vector comprising a nucleic acid encoding, an NFIF polypeptide comprising an amino acid sequence of Figure 1 (SEQ ID NO: 1). Current claims 26-28, as amended, are now considered to be drawn to non-elected invention group V as set forth in the original Election/Restriction mailed 6/26/2003. Group V, which included claims 7-9 and 12, is drawn to a method a method of increasing expression of NFkB in a patient comprising introducing an expression vector encoding NFIF-14b polypeptide, classified in class 435, subclass 375.

2. Group V was withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the Paper filed 8-29-03.

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3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

4. The Declarations filed on 12-22-04 under 37 CFR 1.131 are sufficient to overcome the Sugano et al. reference, therefore the rejection of claims 1, and 3 under 35 USC 102(a) is withdrawn.

Sequence Listings

5. Applicants have not amended the specification to provide sequence identifiers in the brief description of the drawings (pages 5-6) for the sequence disclosures set forth in the figures, specifically for Figures 1-3 and 7.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Bandman et al. (US Patent No. 6,132,964).

Instant claim 1 is drawn to an isolated nucleic acid encoding NF1F-14b polypeptide comprising an amino acid sequence as shown in Figure 1 (SEQ ID NO: 1); claim 3 is drawn to the nucleic acid of claim 1 wherein said nucleic acid is a cDNA.

Bandman et al. discloses a polynucleotide of 1764 base pairs in length (SEQ ID NO: 13 of Bandman et al. see col. 63-66) that is 99.9% identical to SEQ ID NO: 3 of the instant application. Absent evidence to the contrary the polynucleotide of Bandman et al. is an isolated nucleic acid encoding NF1F-14b polypeptide comprising an amino acid sequence as shown in Figure 1 (SEQ ID NO: 1 of the instant application). Furthermore, the Bandman et al. sequence was isolated as a cDNA clone from a human pituitary gland cDNA library (see col. 11, Table 1).

9. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Bandman et al. (US Patent No. 6,518,029).

Instant claim 1 is draw to an isolated nucleic acid encoding NF1F-14b polypeptide comprising an amino acid sequence as shown in Figure 1 (SEQ ID NO: 1); claim 3 is drawn to the nucleic acid of claim 1 wherein said nucleic acid is a cDNA.

Bandman et al. discloses a polynucleotide of 1764 base pairs in length (SEQ ID NO: 13 of Bandman et al. see col. 65-68) that is 99.9% identical to SEQ ID NO: 3 of the instant application. Absent evidence to the contrary the polynucleotide of Bandman et al. is an isolated nucleic acid encoding NF1F-14b polypeptide comprising an amino acid sequence as shown in

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Figure 1 (SEQ ID NO: 1 of the instant application). Furthermore, the Bandman et al. sequence was isolated as a cDNA clone from a human pituitary gland cDNA library (see col. 11, Table 1).

Drawings

10. The Drawings submitted by Applicants on 10-05-2001 are considered acceptable by the examiner. It is noted that the Notice of Draftsperson's Patent Drawing Review mailed 11-17-2003 was based upon the Drawing submitted by Applicants 3-30-01, the Draftsperson did not consider the drawings submitted by Applicants on 10-05-2001.

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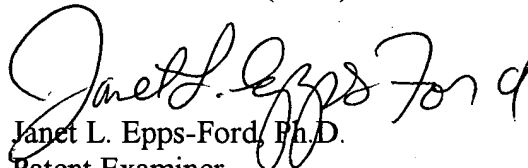
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Janet L. Epps-Ford, Ph.D.
Patent Examiner
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JLE